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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,748	11/19/1999	WALTER DIEMBECK	BEIERSDORF56	4709

7590

09/04/2003

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EXAMINER

LAMM, MARINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/367,748

Applicant(s)

DIEMBECK ET AL.

Examiner

Marina Lamm

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-8,11-15 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-8,11-15 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/03 has been entered.
2. Claims pending are 1, 2, 4-8, 11-15 and 18-24. Claims 3, 9, 10 and 25-27 have been cancelled. Claims 1 and 19 have been amended.

### ***Claim Objections***

3. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1, as amended, recites a method for the treatment of rosacea and couperose. Claim 18 recites the limitation "method according to claim 1, which is for the treatment of rosacea and couperose." Thus, Claim 18 fails to further limit the subject matter of Claim 1 because it fails to recite any additional method steps and/or conditions.

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 2, 4-8, 11-15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giacomoni (WO 96/26711), both the reference and the translation thereof supplied by the Applicant.

Giacomoni teaches cosmetic compositions containing a combination of at least one cosmetic or pharmaceutical substance such as an antioxidant (e.g. vit E and/or A) and/or a sun block, and 10<sup>-6</sup>-10% by weight of at least one NO synthase inhibitor in cosmetically acceptable carrier. See Abstract; pp. 4, 8 of the translation. The compositions of Giacomoni may be used for the treatment of various skin conditions, including rosacea. See p. 8, last paragraph, of the translation. The NO synthase inhibitors of Giacomoni include N<sup>G</sup>-monomethyl-L-arginine, N<sup>G</sup>-nitro-L-arginine and its methyl ester, N<sup>G</sup>,N<sup>G</sup>-dimethyl-L-arginine and N<sup>G</sup>-amino-L-arginine which can be used either alone or in a mixture. See p. 5 of the translation. The compositions of Giacomoni may be formulated as sun creams. See p. 6, second paragraph from the bottom, of the translation. While the Giacomoni reference encompasses the claimed method of treating rosacea by applying to a patient a NO-synthase inhibitor-containing composition, it is deficient in the sense that it does not provide guidance as to selecting rosacea among various other skin conditions. However, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the NO-synthase inhibitor-containing compositions of Giacomoni for the treatment of rosacea with a reasonable expectation of success because Giacomoni teaches that his compositions "are ideal for use" in the treatment of "dermatological complaints associated with a keratinisation disorder relating to differentiation and proliferation, particularly for treating...rosaceous acne." With respect to the limitation "couperose", which is not explicitly taught by the reference, the method of treating rosaceous

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acne (rosacea) encompassed by the reference, will inherently include the treatment of couperose because rosacea, by definition, includes symptoms of couperose (i.e. dilation of superficial capillaries). See Stedman's Medical Dictionary 27<sup>th</sup> Edition.

6. Claims 1, 2, 4-8, 11-15 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (WO 97/15280 as translated by US 2002/0037854).

WO 97/15280 is the PCT counterpart to US 2002/0037854. WO 97/15280 is a prior art under 35 USC §102(a) as a result of its May 1, 1997 publication date. US 2002/0037854 is not a prior art but will be used as a translation of WO 97/15280, which is published in French. While any reference hereinafter to section numbers will be based upon the US patent publication disclosure, such reference should be interpreted as including the corresponding disclosure of the aforementioned PCT counterpart.

Breton et al. teach a method for treating sensitive skin, such as hyperseborrheic or acneic skin, by topically applying a cosmetic composition comprising 10<sup>-6</sup>-10% by weight of an inhibitor of NO synthase as an active ingredient. See Abstract; [0009]; [0016]. NO synthase inhibitors of Breton et al. include N(5)-(1-iminoethyl)-L-ornithine, 7-nitroindazole, methyl ester of N<sup>G</sup>-nitro-L-arginine, N<sup>G</sup>,N<sup>G</sup>-dimethyl-L-arginine and N<sup>G</sup>-monomethyl-L-arginine. See [0023]-[0029]. The inhibitors can be used either alone or as a mixture. See [0030]. The compositions of Breton et al. may also contain antioxidants and/or filters and may be in the form of sun protection creams or lotions. See [0038]; [0045]. The compositions of Breton et al. may be used for treating certain skin diseases including rosacea. See [0038]. While the Breton et al. reference encompasses the claimed method of treating rosacea by applying to a patient a NO-synthase inhibitor-containing composition, it is deficient in the sense that it does

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not provide guidance as to selecting rosacea among other skin conditions. However, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the NO-synthase inhibitor-containing compositions of Breton et al. for the treatment of rosacea with a reasonable expectation of success because Breton et al. teach that their compositions can be used for the treatment of sensitive skin, such as hyperseborrheic or acneic skin, and various skin conditions associated with it, such as rosacea. With respect to the limitation "couperose", which is not explicitly taught by the reference, the method of treating rosacea encompassed by the reference, will inherently include the treatment of couperose because rosacea, by definition, includes symptoms of couperose (i.e. dilation of superficial capillaries). See Stedman's Medical Dictionary 27<sup>th</sup> Edition.

7. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giacomoni as applied to claim 19 above, and further in view of either Breton et al. (US 5,795,574 or WO 97/15280 as translated by US 2002/0037854).

Giacomoni applied as above. The reference does not explicitly teach the NO-synthase inhibitors of Claim 20. However, Breton et al. teach using N(5)-(1-iminoethyl)-L-ornithine and 7-nitroindazole interchangeably with methyl ester of N<sup>G</sup>-nitro-L-arginine, N<sup>G</sup>,N<sup>G</sup>-dimethyl-L-arginine and N<sup>G</sup>-monomethyl-L-arginine of Giacomoni for the same art-recognized purpose, i.e. as NO-synthase inhibitors capable of inhibiting cutaneous inflammation. See col. 9, lines

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18-21; col. 11, lines 44-50 of US 5,795,574; [0015]], [0016], [0023]-[0028] of US 2002/0037854.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

9. No claim is allowed at this time.

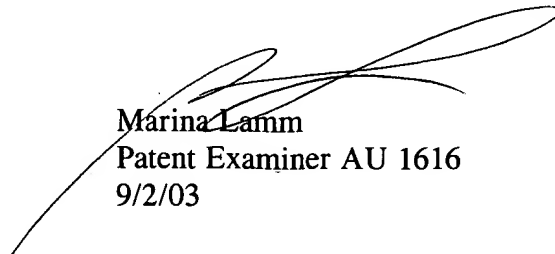
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541.

The examiner can normally be reached on Monday to Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Marina Lamm  
Patent Examiner AU 1616  
9/2/03